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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,182	10/05/2005	Marcia L Kalish	6395-67856-06	6209

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EXAMINER	
SNYDER, STUART	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
06/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,182	KALISH ET AL.	
	Examiner	Art Unit	
	Stuart W. Snyder	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-59* is/are pending in the application.

4a) Of the above claim(s) *1-25,35,37,39,40 and 47-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-29,36,38,41-46 and 55-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/5/2005, 10/16/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Notice to comply*.

DETAILED ACTION

Status of the Claims

1. Applicant's election **without** traverse of Group II (original claims 26-29, 36, and 38; newly added claims 41-46 and 55-59) in the reply filed on 3/28/2007 is acknowledged. Applicant's cancellation of claims 30-34 is also acknowledged. Claims 1-25, 35, 37, 39-40 and 47-54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Specification

2. The disclosure is objected to because of the following informalities: The specification fails to comply with the sequence listing requirements (see page 13, line 16). 37 CFR 1.821 reads, in part:

> **§ 1.821 Nucleotide and/or amino acid sequence disclosures in patent applications.**
>
> **(a) Nucleotide and/or amino acid sequences as used in § § 1.821 through 1.825 are interpreted to mean an unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides.**

Thus, inclusion of the sequence $X_1GCX_4X_5X_6X_7X_8CX_{10}T$ of page 13 in the sequence listing and reference to is as SEQ ID NO:XX is required.

On page 19, line 35 the specification refers to "Table 1 below...". The table on page 20 is entitled Table 2; table 1 is on page 14.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 26-28, 36, 38, 41-46 and 55-59 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. There are no recited steps for the method.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 26-29, 38, 44-45, 55, 57, and 59 rejected under 35 U.S.C. 103(a) as being unpatentable over Simon, et al. (2001) in view of Tam (1988) and Bridon, et al. (1998). The claims are drawn to an immunoassay to detect and differentiate amongst various SIVs; detection and differentiation is based on antibodies binding to synthetic peptides—"comprising about less than 16 amino acids—derived from SIV gp36/41 and gp120 V3 loop, respectively. Additional limitations include presentation of the peptides as Multiple Antigenic Peptides (MAP); MAPs are defined in the specification as each peptide conjugated to a core consisting of 2^x amino groups of lysine covalently attached to the C terminus of either a detection or differentiation peptide thus presenting 2^x copies of each peptides per core. Simon, et al. teaches detection and differentiation amongst various SIVs

based on antibodies binding to synthetic peptides derived from SIV gp36/41 and gp120 V3 loop in an ELISA format. Simon, et al. teaches neither MAP nor synthetic peptides 1 or 14 (the peptide species elected by Applicant's for initial examination). Tam teaches MAPs. Bridon, et al. teaches a 19-mer peptide, the C-terminal portion of which is 81% identical to SEQ ID NO:1 thus meeting the limitation of "having at least 80% sequence identity to one or more of those sequences" referring to SEQ ID NOs:1, 8 or 9 in claim number 55 and considering that 19 is "about" 16.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Simon, et al. by using a MAP format and including a peptide similar to SEQ ID NO:1 and 14 as taught by Tam and Bridon, et al. The skilled artisan would have been motivated to do so to achieve greater antigen density as taught by Tam and capture a large number of SIV isolates as taught by Bridon, et al. There would have been a reasonable expectation of success, given the utility of the including the relatively constant gp41/36 immunodominant region for detection of SIVs and highly variable and serogroup specific gp120 V3 loop for discrimination of SIV serogroups, as taught by Simon, et al.; the flexibility and increased power of MAP technology as taught by TAM and the functionality of Bridon, et al.'s peptide in ELISA assays. Thus, the invention of claims 26-29, 38, 44-45, 55, 57, and 59 was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

5. Claims 36, 41-43, 46, 56, and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simon, et al. (2001), Tam (1988), and Bridon, et al. (1998) as applied to claims 26-29, 38, 44, 55, 57, and 59 above, and further in view of Silvera, et al., Hirsch, et al., and Tsujimoto, et al. Claims 36, 41-43, 46, 56, and 58 are drawn to a method of detection of and discriminating amongst SIV using an immunological assay to capture anti-SIV envelope antibodies with specific, non-HIV derived peptides. Simon, et al. (2001), Tam (1988) and Bridon, et al. (1998) do not teach the use of these specific peptides. Silvera, et al. teaches a fine analyze of the antibody response to natural infection or vaccination of macaques with SIV or gp160, the precursor of mature gp41/36/120 envelope protein. Their approach used overlapping peptides encompassing the entire sequence of SIV envelope protein and synthetic peptides predicted to be highly immunogenic; they specifically excluded HIV-derived peptides from their studies. They, and many others (see for example, Miller, et al.), identified and characterized immunodominant regions, including the region used by Applicants, of SIV gp41/36 as well as the highly variable V3 loop of gp120 that, among other regions of the protein, is characteristic of specific serogroups of the virus. Hirsch, et al., and Tsujimoto, et al. each teach the evolution of the SIV genome. The investigations of Silvera, et al. Simon, et al., and Bridon, et al., along with many others in the field were conducted to better understand the SIV/non-human primate model used for designing vaccines directed against HIV for use in humans and have echoed many previous studies of the immune response in

humans to naturally occurring HIV infections (see, for example, the introduction to Silvera, et al.).

It would have been obvious to one of ordinary skill in the art to modify the methods taught by Simon, et al., Tam, and Bridon, et al. by inclusion of peptides comprising those taught ny Silvera, et al. in order to include more recent isolates of SIV. One would have been motivated to do so to improve the sensitivity and specificity of the gp41/36 and gp120 given the suggestion by Simon, et al. to use this approach to detect serologically diverse strains of SIV (see introduction). There would have been a reasonable expectation of success given the knowledge that the strategy works to distinguish SIVs from each other and HIV-1/2 as taught by Simon, et al. and also given the knowledge that the SIVs continue to evolve in nature as taught by Hirsch, et al., Tsujimoto, et al. and others. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

6. No claims are allowed.

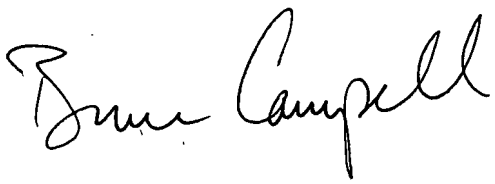
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart W. Snyder whose telephone number is (571) 272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stuart W Snyder
Examiner
Art Unit 1648

SWS



Notice to Comply	Application No. 1055182	Applicant(s) Kalish et al.	
	Examiner Stuart W. Snyder	Art Unit 1648	

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e). The correct SEQ ID NO:2 is present in the paper copy of the of the sequence listing only. Therefore a search of the correct sequence is not possible.

☐ 7. Other:

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application**.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216 or (703) 308-2923
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